UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

x

In re Elysium Health-Chromadex Litigation 17 Civ. 7394 (CM)

x

DECISION AND ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

McMahon, C.J.:

On September 27, 2017, Plaintiff Elysium Health, Inc. ("Elysium") filed a complaint ("Complaint") against Defendant Chromadex, Inc. ("CMDX"), alleging violations of § 43(a) of the Lanham Act, as well as state law claims of trade libel, deceptive business practices under New York General Business Law § 349, and tortious interference with prospective economic relations.

Presently before the Court is CMDX's Motion for Summary Judgment based on a claim of immunity under the *Noerr-Pennington* doctrine.

For the reasons that follow, CMDX's Motion is GRANTED.

I. Background

The Court presumes the parties' familiarity with the details of this case, which were outlined in the Court's prior order (*see* Dkt. No. 44), and writes merely to provide a brief recitation of the facts that are pertinent to Defendant's present Motion.

Elysium sells a product called Basis, an anti-aging dietary supplement comprised of two ingredients, pterostilbene ("PT") and nicotinamide riboside ("NR"). (Declaration of Troy Rhonemus ("Rhonemus Decl.") ¶ 56, Dkt. No. 51.) CMDX develops, sells, and produces these ingredients in bulk, licensed as NIAGEN® and pTeroPure®, for use in consumer products. (*Id.* ¶ 8.) CMDX formerly supplied Elysium with these ingredients, but their business relationship

soured and ultimately ended in 2016. (*See id.* ¶¶ 58–60.) Thereafter, CMDX began selling TruNiagen, its own anti-aging NR product. (*Id.* ¶ 7.)

Beginning in approximately August 2017, Elysium manufactured a new version of Basis using NR and PT from an unknown supplier. (*Id.* ¶ 62.) Around this time, CMDX conducted in-house testing of the new version of Basis, which revealed that the new NR and PT ingredients used by Elysium were chemically different from NIAGEN® and pTeroPure®, and that Basis now contained toluene, an industrial solvent that potentially poses "serious health concerns" when ingested. (*Id.* ¶¶ 48, 62.) Thereafter, CMDX filed a citizen petition ("Citizen Petition" or the "Petition") with the FDA, asking the agency to make the following two determinations on the basis of CMDX's in-house testing of Basis:

> *i.* That Elysium's Basis product is adulterated under 21 U.S.C. § 342(a) and (f) based on the undeclared presence of toluene in the product at the level of 96–144 mg/kg; and
>
> *ii.* That Elysium's Basis product contains a new dietary ingredient under 21 U.S.C. § 350b for which Elysium had not submitted a New Dietary Ingredient Notification ("NDIN"), thereby rendering the product adulterated under §§ 342(f)(1)(B) and 350(a).

(Declaration of Joseph N. Sacca ("Sacca Decl.") Ex. 1 at 2, Dkt. No. 53 (Citizen Petition) (quotation marks omitted).)

In support of its requests, the Citizen Petition noted that the FDA has not set any allowable level of exposure to toluene through oral ingestion of a dietary supplement, and cited a 2015 Center for Disease Control ("CDC") publication touting the dangers of toluene. (*Id.* at 6.) CMDX also asked the FDA to "take all appropriate remedial action, including [ordering] that Elysium cease distribution of its Basis product and take other appropriate enforcement action, including seizure of violating products and an injunction against the manufacturers and distributors under 21 U.S.C. §§ 332 and 334." (*Id.* at 2.)

In response, Elysium filed a lawsuit on September 27, 2017, alleging that the Citizen Petition was false, misleading, and filed for the sole purpose of harming Elysium. (*See* Compl., Dkt. No. 1.) Elysium's Complaint articulated three bases in support of this contention.

First, it alleged that the levels of toluene that CMDX had claimed were contained in Basis were consistent with pharmaceutical standards set forth by the International Conference on Harmonisation if Technical Requirements for Pharmaceuticals for Human Use ("lCH"), a non-profit association under Swiss law that, as its name suggests, makes recommendations about harmonizing competing regulatory requirements for pharmaceutical products, and that the FDA regularly relies on these standards for dietary supplements where no other applicable standards exist. (*Id.* ¶¶ 54–55.)

Second, Elysium averred that, based on Certificates of Analysis ("COAs") provided by CMDX to its customers, CMDX's pTeroPure® contains similar levels of toluene, so CMDX could not actually have believed that Basis was unsafe or that the Citizen Petition could be successful on the merits. (*Id.* ¶ 65.)

Third, it contended that CMDX had no expectation that the FDA would grant its Citizen Petition because CMDX knew (or, as a regulatory consultant, should have known) that the FDA does not grant citizen petitions that seek the commencement of enforcement actions, including actions for seizure or injunctive relief. (*Id.* ¶¶ 37–44 (citing 21 C.F.R. § 10.30(k).)

On October 26, 2017, CMDX moved to dismiss the Complaint under Fed. R. Civ. P. 12(b)(6). As part of that motion, CMDX argued that, even if Elysium could state a viable claim for unfair competition, CMDX's filing of the Citizen Petition qualifies for protection under the *Noerr-Pennington* doctrine, which safeguards the First Amendment right to petition the government for a redress of grievances by immunizing citizens from liability attending to that

right. (Mem. of Law in Supp. Def.'s Mot. Dismiss ("Def.'s MTD") at 4, Dkt. No. 20.) *See also* U.S. Const. amend. I. Elysium countered that CMDX's activity fell under *Noerr-Pennington*'s narrow "sham exception," which denies immunity for one's attempts to influence governmental action where doing so is a "mere sham to cover an attempt to interfere directly with the business relationships of a competitor." *See E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).

Meanwhile, on January 16, 2018, nearly four months after Elysium's Complaint was filed, CMDX submitted a supplemental citizen petition ("Supplemental Petition") to the FDA, which asked the FDA to:

> *i.* Issue agency guidance or otherwise announce publicly that ICH guidelines do not apply to dietary supplements;
>
> *ii.* Issue an order that NR is not reasonably expected to be safe if it contains new impurities, such as toluene, that have not been reviewed under the NDIN process; and
>
> *iii.* Finalize its NDIN guidance and clarify its enforcement policy with respect to dietary supplement manufacturers that include a New Dietary Ingredient in their products without complying with the notification requirements that are outlined in Section 413(a) of the 2016 U.S. Food and Drug Administration Act.

(Rhonemus Decl. ¶ 74, *id.* Ex. P (Supplemental Petition) (internal quotation marks omitted).)

On January 25, 2018, Elysium submitted a comment to the Supplemental Petition, informing the FDA that it removed toluene from its new version of Basis. (Rhonemus Decl. ¶ 77; *id.* Ex. Q at 1 (Elysium's comment to Supplemental Petition).) Elysium explained, "Although [it] believes that the ICH Guidelines establish the safety of toluene at the minimal levels previously found in Basis, Elysium elected to eliminate the presence of toluene from Basis as part of its continuing efforts to ensure superior product quality." (*Id.*)

On September 27, 2018, the Court denied in part CMDX's motion to dismiss and converted the remainder of the motion – the argument that CMDX was immune from liability under the

Noerr-Pennington doctrine – to a motion for summary judgment, since that particular issue called upon the Court to consider evidence outside the pleadings. (*See* Order on Mot. to Dismiss, dated Sept. 27, 2018, Dkt. No. 44.)

That issue is presently before the Court.

II. Discussion

As the Court noted in its earlier Order, the sole issue to be considered is whether the filing of the Citizen Petition is "objectively baseless" and, thus, amenable to *Noerr-Pennington*'s "sham" exception, thereby disqualifying it from the doctrine's immunity. Elysium argues that summary judgment is not appropriate, because CMDX has not established that there is no genuine issue of material fact as to whether the Citizen Petition was objectively baseless.

The familiar summary judgment standard applies.

Summary judgment is available only in the absence of a "genuine issue of material fact" and where the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986). The moving party – here, CMDX – has the initial burden of demonstrating the absence of disputed issues of material fact. *Celotex v. Catrett*, 477 U.S. 317, 323 (1986). A dispute concerning a material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Aldrich v. Randolph Cent. Sch. Dist.*, 963 F.2d 520, 523 (2d Cir. 1992) (quoting *Anderson*, 477 U.S. at 248). A genuine issue for trial exists if, based on the record as a whole, a reasonable jury could find in favor of the non-movant. *See Anderson*, 477 U.S. at 248.

Elysium, as the party against whom summary judgment is sought, is entitled to all reasonable inferences, and the Court must view the evidence in the light most favorable to it. *Anderson*, 477 U.S. at 255. Elysium, however, must go beyond the pleadings and "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec.*

Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Rather, it must present "specific facts showing that there is a genuine issue for trial." *Beard v. Banks*, 548 U.S. 521, 529 (2006). Conclusory or speculative evidence with no basis in fact will not suffice. *Anderson*, 477 U.S. at 249–50.

In moving for summary judgment in the context of the *Noerr-Pennington* doctrine, CMDX bears the ultimate burden of establishing the absence of disputed material facts that bear on the applicability of *Noerr-Pennington* immunity.

As articulated in *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136–39 (1961) and *United Mine Workers v. Pennington*, 381 U.S. 657, 669–70 (1965), the *Noerr-Pennington* doctrine holds that attempts to influence legislative, executive, administration or judicial action are immune from liability by virtue of the First Amendment right to petition the government for a redress of grievances. *See also Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972) ("Certainly the right to petition extends to all departments of the Government."). While *Noerr-Pennington* was an antitrust case, state and federal courts routinely hold that it extends further and applies to a wide range of civil actions under both state and federal law. *See, e.g.*, *Bill Johnson's Restaurants, Inc. v. NLRB*, 461 U.S. 731 (1983); *Suburban Restoration Co. v. ACMAT Corp.*, 700 F.2d 98, 101–102 (2d Cir. 1983); *Friends of Rockland Shelter Animals, Inc. (FORSA) v. Mullen*, 313 F. Supp. 2d 339 (S.D.N.Y. 2004). The Second Circuit has specifically recognized that the doctrine applies to citizen petitions before the FDA. *See Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59–62 (2d Cir. 2016).

Noerr-Pennington immunity, though formidable, is not an absolute shield to liability. It will not attach where "petitioning activity ostensibly directed toward influencing governmental action, is a mere sham to cover . . . an attempt" to violate federal law. *Prof'l Real Estate Investors,*

Inc. v. Columbia Pictures Indus. ("*PRE*"), 508 U.S. 49, 56 (1993) (internal quotations omitted). In *PRE*, the Supreme Court established a two-part test for determining what constitutes sham activity under *Noerr-Pennington*:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and a [] claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation.

Id. at 60. "[E]vidence of anticompetitive intent or purpose alone cannot transform otherwise legitimate activity into a sham." *Id.* at 49.

The sham exception should be construed narrowly so as to avoid intrusion upon, or a chilling of, one's right to petition under the First Amendment. *See id.* at 56; *see also BE & K Const. Co. v. N.L.R.B.*, 536 U.S. 516, 532 (2002). The burden of proving the exception rests with the party attempting to invoke it. *See id.* at 60; *see also Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 791 F.2d 288, 292–93 (4th Cir. 1986) (holding that the burden of proving the sham exception is properly on the party attempting to invoke it) (citing *Cal. Motor Transp.*, 404 U.S. at 518 (Stewart, J., concurring)); *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015) ("[*PRE*]'s exacting two-step test properly places a heavy thumb on the scale in favor of the defendant.").

While various courts outside this Circuit have generally regarded the applicability of the sham exception as a question of fact for the jury, *see, e.g.*, *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011), a court may decide this issue as a matter of law where "there is no dispute over the predicate facts underlying the legal proceeding." *PRE*, 508 U.S. at 62.

a. The Citizen Petition Was Not Objectively Baseless

CMDX argues that the Citizen Petition was not objectively baseless as a matter of law for two independent reasons. First, it submits that the Citizen Petition was reasonably calculated to

elicit a favorable outcome, and, indeed, succeeded in doing so, and thus was not a sham. (Def.'s Mem. of Law in Supp. Summ. J. ("Def.'s Br.") at 8, Dkt. No. 49.) Second, it argues that the two determinations it sought from the FDA were legally viable, as was its request for an agency enforcement action. (*Id.* at 3–7.)

The Court need not address the latter contention, as it finds the first to be persuasive.

Under *PRE*, the objective baselessness standard is that "no reasonable litigant could realistically expect success on the merits[,]" which, in turn, is defined as being "reasonably calculated to elicit a favorable outcome." *Id.* at 60. As the Supreme Court wrote in *PRE*, "A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham." 508 U.S. at 60 n.5.

Prompting Elysium to remove toluene from Basis is, by definition, a favorable outcome, because the Citizen Petition expressly stated that CMDX hoped to cause the removal of Basis from the market so long as it "contain[ed] a deleterious substance that render[ed] it injurious to health." (Sacca Decl. at 5.) Elysium concedes in its comment to the Supplemental Petition that, when it opted to remove toluene from Basis, it did so to help "ensure superior product quality." (Rhonemus Decl. Ex. Q at 1.) Superior product quality appears to be a euphemism for a potentially safer product – in other words, an admission that the presence of toluene in Basis posed potential harm to consumers. Either way, CMDX achieved the very outcome it petitioned for – the removal of toluene from a dietary supplement sold directly to consumers that it believed rendered that product potentially "injurious" to public safety. Having achieved a favorable outcome, the Citizen Petition cannot be said to be objectively baseless. *PRE*, 508 U.S. at 60.

Three principles guide this decision.

One, petitioning activity that actually produces a favorable outcome is axiomatic of the type of petitioning activity that is designed to elicit a favorable outcome and, thus, susceptible to *Noerr-Pennington* immunity. On this score, *EDF Renewable Dev., Inc. v. Tritec Real Estate Co., Inc.*, 147 F. Supp. 3d 63 (E.D.N.Y. 2015) is illuminating. In that case, the plaintiff, a real estate project developer, was awarded a contract for a project for solar photovoltaic power installations on Long Island by the Long Island Power Authority, pursuant to which the two parties entered into seven lease agreements for the installation and operation of solar carport facilities at various sites. *Id.* at 64. One of those sites was adjacent to a development project owned by the defendant. The defendant lobbied the Suffolk County Executive to breach the lease arrangement in connection with the development site adjacent to his. *Id.* at 65–66. The defendant's lobbying campaign was a success – Suffolk County officials dragged their feet in approving the plaintiff's building permits, and eventually told plaintiff it would no longer honor his lease agreement. *Id.* at 66.

The plaintiff sued the defendant for tortious interference with the lease, the defendant invoked the *Noerr-Pennington* doctrine, and the plaintiff pressed for application of the doctrine's sham exception. The court sided with the defendant, concluding that the defendant's efforts to thwart the plaintiff's development project were immunized under *Noerr-Pennington*, despite the clear anti-competitive motivations at play. *Id.* at 70. In so holding, the court intimated that part of the reason that the defendant's conduct was not considered an objectively baseless sham was because its efforts to thwart the development *actually succeeded*. *See id.* Noting that "[t]he very purpose of the meeting was to 'pressure,' 'persuade,' and 'convinc[e]' the County" to block plaintiff's development, the court concluded that, "[S]ince plaintiff attributes the County's failure to issue it a building permit for the [site] to defendant's [petitioning conduct] . . . defendant's conduct cannot be considered a 'sham.'" *Id.*

That principle applies with equal force here. The Citizen Petition states, in no uncertain terms, that it sought to cause the removal of a potentially dangerous product from the market. Thereafter, Elysium removed from Basis the potentially harmful ingredient that gave rise to the Citizen Petition in the first place. CMDX contends that the Citizen Petition accomplished what it sought to do. While Elysium does not expressly attribute to the filing of the Citizen Petition its decision to remove toluene from Basis, denying the connection between the two events would be unreasonable. Based on these straightforward facts, CMDX's conduct cannot be considered a sham. The Court need not speculate as to whether the Citizen Petition was designed to elicit a favorable outcome because the proof is in the pudding – it actually did.

The second principle guiding the Court's decision is that case law establishes that a favorable outcome need not materialize at the direction of a government entity or as a result of government action for it to qualify for *Noerr-Pennington* protection. Various courts, both in this Circuit and in others, have reached this conclusion in the context of settlement, holding that settlement of a purportedly objectively baseless lawsuit constitutes a favorable outcome within the meaning of *Noerr-Pennington* and therefore insulates the activity from application of the sham exception. *See In re Fresh Del Monte Pineapple*, No. 04-Md.-1628 (RMB)(MHD), 2007 WL 64189, at *19 (S.D.N.Y. Jan. 4, 2007), *subsequently aff'd sub nom. Am. Banana Co. v. J. Bonafede Co.*, 407 F. App'x 520 (2d Cir. 2010); *Mover's & Warehousemen's Ass'n of Greater New York, Inc. v. Long Island Moving & Storage Ass'n, Inc.*, No. 98 Civ. 5373 (SJ), 1999 WL 1243054, at *6 (E.D.N.Y. Dec. 16, 1999); *see also Theme Promotions, Inc. v. News Am. Mktg. FSI*, 546 F.3d 991, 1008 (9th Cir. 2008); *New West, L.P. v. City of Joliet*, 491 F.3d 717, 722 (7th Cir. 2007); *STMicroelectronics, Inc. v. Avago Tech. U.S., Inc.*, No. 10 Civ. 5023(JF)(PSG), 2011 WL

1362163, at *2 (N.D. Cal. Apr. 11, 2011); *Toyo Tire & Rubber Co. v. CIA Wheel Grp.*, No. SACV 15-246-JLS (DFMX), 2015 WL 4545187, at *3 (C.D. Cal. July 8, 2015).

Similarly instructive is *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1341 (S.D. Fla. 2004), a multi-district antitrust dispute stemming from a defendant-drug manufacturer's various attempts to protect its patents' exclusivity pertaining to its brand name drug, and the competing efforts of generic drug manufacturers to develop and launch bioequivalent drugs. The generic manufacturers alleged, *inter alia*, that the defendant filed seventeen "sham" patent infringement lawsuits to thwart competitors from entering the market, thereby illegally maintaining a patent monopoly beyond the life of its patents. *Id.* at 1342–43. The court, determining that the defendant's efforts were immunized under *Noerr-Pennington*, rejected application of the sham exception, finding that none of the defendant's lawsuits was objectively baseless as a matter of law.

Importantly, the court characterized some of those lawsuits as successful, and therefore not objectively baseless, because – even though they did not result in a favorable verdict – defendant still obtained certain relief or information it sought by filing the lawsuits. *Id.* at 1357. "By definition, [the defendant] 'won' seven of these lawsuits because they were 'reasonable efforts at petitioning for redress.'" *Id.* at 1357–58. (citing *PRE*, 508 U.S. at 61). One of the lawsuits even prompted one of the generic drug manufacturers to agree to "modify its process for manufacturing its generic tablet," earning the defendant a favorable outcome irrespective of a winning verdict. *Id.* at 1357. As part of its opposition to the application of *Noerr-Pennington* immunity, the plaintiff argued that the outcomes of those lawsuits were not favorable, since they had not come "from the court itself." *Id.* at 1357 n.13. The Court rejected this argument, writing that it "cannot agree with Plaintiffs that a plaintiff who has filed suit and receives the relief sought (*e.g.*, monetary

compensation, a change in conduct, etc.) could only have been deemed to have 'won' under *PRE* if it continued to litigate the case and received a favorable judgment from the court."). *Id.*

This principle has been reaffirmed by other courts in other contexts. *See, e.g.*, *P.R. Tele. Co. v. San Juan Cable Co.*, 196 F. Supp. 3d 248, 326 (D.P.R. 2016), *aff'd*, 874 F.3d 767 (1st Cir. 2017). Applying that principle here, it matters not a whit that Elysium removed toluene from Basis acting on its own volition rather than at the direction of the FDA. The critical point is that Elysium acted in response to CMDX's filing of the Citizen Petition, and did so in a manner that scored a win for CMDX.

Which leads the Court to the third and final guiding principle.

The *Noerr-Pennington* doctrine is outcome-focused, not means-focused; courts asking whether petitioning activity was objectively baseless must consider whether it was designed to elicit a favorable outcome irrespective of the propriety of the means by which that outcome was sought. Elysium contends that CMDX's Citizen Petition was objectively baseless because the FDA could not grant all of the relief requested in the Citizen Petition, since seizure and injunctive relief are judicial remedies that do not fall within the scope of relief allowed by a citizen petition. (Mem. of Law. In Opp. Def.'s Mot. for Summ. J. ("Pl.'s Opp.") at 8, Dkt. No. 52.) That CMDX is alleged to have employed arguably improper tactics in seeking this outcome – asking for relief that may have been beyond the purview of the citizen petition process – does not render its efforts any less susceptible to *Noerr-Pennington* protection.

As the Supreme Court has instructed, "[A] 'sham' situation involves a defendant whose activities are 'not genuinely aimed at procuring favorable government action' at all, not one 'who genuinely seeks to achieve his governmental result, but does so through improper means.'" *City of Columbia v. Omni Outdoor Advert., Inc.*, 499 U.S. 365, 380 (1991) (quoting *Allied Tube &*

Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 508 nn. 4 &10 (1988)). Whether or not the FDA was empowered to 'grant' the relief requested in the Citizen Petition is therefore beside the point; what matters is whether CMDX's efforts were genuinely aimed at procuring the result it ultimately achieved. Since Elysium has not identified a genuine of issue of material fact to suggest that CMDX acted solely to damage Elysium and without a genuine interest in the removal of toluene from Basis, the sham exception is inapplicable.

CONCLUSION

Based on the foregoing, CMDX's Motion for Summary Judgment is GRANTED.

The Clerk of Court was directed to close CMDX's motion to dismiss at Dkt. No. 19 when the motion to dismiss was denied in part and the *Noerr-Pennington* issue was converted to a motion for summary judgment. Unfortunately, the Court neglected to tell the Clerk to assign a new motion number to the converted motion. The Clerk is hereby directed to reopen the motion at Dkt. No. 19, and to enter an order granting the Defendant's converted motion for summary judgment.

Dated: January 3, 2019

Chief Judge

BY ECF TO ALL PARTIES